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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,304	06/27/2003	James L. Carlyon	20518/42 (S-8446)	8017
7590	02/24/2005		EXAMINER	
Mark S. Leonardo, Esq. Brown Rudnick Berlack Israels LLP One Financial Center Boston, MA 02111			KENNEDY, SHARON E	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/609,304	CARLYON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharon Kennedy	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 June 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/21/03; 12/16/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

### ***Drawings***

The drawings are objected to because they are poorly reproduced and the details are difficult to examine.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

Claims 1, 4-7, 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Saulenas et al., US 2003/0078540 A1. See especially figures 18-24 of Saulenas, paragraphs [0071]+. Regarding claim 1, Saulenas discloses the housing (barrel 20) having a cavity (aperture 90, shown labeled in figure 7) in a sidewall thereof; a cover (wings 224, figure 21) having a movable tab (actuating arm 228); a hub 36 having a movable projection (actuator button 64). Note that the Saulenas actuating arm 228

interacts with the actuator button 64 via extension through aperture 90. Regarding claim 4, Saulenas figures 18+ do not show the distal end of the barrel 20, however, see Saulenas figure 16. The claimed groove is anticipated by the distal perpendicular surface of Saulenas stop flange 102 in concert with locking fingers 108. Regarding claim 7, applicant is evidently trying to claim chamber 108 of figure 11, however, as defined in the claim, it does not distinguish over Saulenas. Any of the spaces between wings 224 and barrel 20 anticipate the claim. See Saulenas figure 20, for example. Regarding claim 12, Saulenas discloses a lip, unlabeled, at the distal end of barrel 20.

#### ***Claim Rejections - 35 USC § 103***

Claims 2, 3, 8, 14-18, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saulenas '540. These claims recite multiple projections, cavities and tabs. It is *prima facie* obvious for one of ordinary skill in the art to multiply the actuating buttons, arms and apertures of Saulenas, adding a second actuating mechanism on opposite sides, for example. See MPEP 2144.04, VI. B., entitled, "Duplication of Parts." Mere duplication of parts has no patentable significance unless a new and unexpected result is produced. Applicant's specification has not set forth any unusual effect resulting from the multiple parts. It seems to be a matter of design choice as set forth in applicant's paragraph [0046] of the published application. Accordingly, claims 2, 3, 14-18 and 20-23 claims must be rejected. Regarding claims 8 and 24, it is *prima facie* obvious to make a device from one piece as opposed to two. See MPEP 2144.04 V. B., entitled, "Making Integral." Making a device integral as opposed to separable is

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merely a matter of obvious engineering choice. Applicant's specification has not set forth any unusual effect resulting from making the parts monolithic; accordingly, these claims must be rejected.

Claims 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saulenas '540 in view of Halseth, US 6,524,276. Saulenas fails to disclose a device that orients the needle out of axial alignment with the housing distal aperture. Halseth discloses a similar device that exemplifies that it is well known to provide this feature in order to more securely house the needle after use. It would be obvious to one of ordinary skill in the art to apply the Halseth needle orientation mechanism with the Saulenas device so that Saulenas could more securely house the needle after use.

#### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571/272-4955.

Information regarding the status of an application may be obtained by going to [www.uspto.gov](http://www.uspto.gov), clicking on "Status &IFW", entering the application number, and then clicking on one of the tabs to retrieve the appropriate information.

  
Sharon Kennedy  
Primary Examiner  
Art Unit 3762

Sek